K003428

NOV 2 4 2000

Summary of Safety and Effectiveness

Sponsor: Biomet, Inc.
Airport Industrial Park
P.O. Box 587
Warsaw, IN 46581-0587

Contact Person: Dalene T. Binkley
(800) 348-9500, ext. 1612

Device Name: ISS Offset Heads

Classification Name: Prosthesis, Shoulder, Hemi-, Humeral, Metallic Uncemented

Device Product Code: (21 CFR 888.3560)

Indications for Use:

1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
2) Rheumatoid arthritis
3) Revision where other devices or treatments have failed
4) Correction of functional deformity
5) Treatment of acute fracture of the humeral head unmanageable using other treatment methods
6) Cuff tear arthropathy

Device Description: : ISS Offset Heads are a modification of standard modular heads. Rather than a modular head with a centered post for attachment to the humeral stem, the post is placed 4mm off the center point. This provides a greater amount of bearing surface on one side of the head. This gives the surgeon the ability to more closely reconstruct the natural anatomy of the patient's shoulder and potentially reduce the risk of dislocation.

To replicate the trialed orientation of the ISS Offset Head, an alignment mechanism (with an alignment pin sticking up) is provided which fits into an asterisk-shaped hole in the trunion of the (Mod II Plus-C) humeral stem (which may be aligned in one of 8 locations located 45° apart.). The hole on the undersurface of the head then fits over the pin thus orienting the head. The pin aligns the head into the pre-determined location. It does not provide anti-rotation.

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Potential Risks: Potential Risks: The potential risks associated with this device are the same as with any joint replacement device. These include, but are not limited to:

Reaction to bone cement	Blood vessel damage	Bone fracture
Deformity of the joint	Soft tissue imbalance	Infection
Cardiovascular disease	Delayed wound healing	Hematoma
Fracture of the cement	Metal sensitivity	Dislocation
Implant loosening/migration	Fracture of the components	Excessive wear
Tissue growth failure	Nerve damage	

Predicate Device(s): Kirschner Neer-III Modular Proximal (K874643).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Dalene T. Binkley
Regulatory Specialist
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581

Re: K003428
Trade Name: ISS Offset Heads
Regulatory Class: Class II
Product Code: HSD
Dated: October 31, 2000
Received: November 3, 2000

Dear Ms. Binkley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) NUMBER (IF KNOWN): K003428

DEVICE NAME: ISS Offset Heads

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (Per 21 CFR 801.109)

OR

Over-The-Counter-Use ____ (Optional Format 1-2-96)

for Mark N Milhous

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K003428